

APR 10 2014

510(k) Summary

Submitter information

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Submission date

The date of the Traditional 510(k) submission is 19th of July, 2013.

Submission information

<i>Trade Name</i>	SurgiCase Orthopaedics system, SurgiCase Connect, SurgiCase Guides
<i>Common Name</i>	Orthopaedic surgical planning and instruments guide
<i>Classification Name</i>	Orthopaedic surgical planning and instruments guide
<i>Product code</i>	PBF

Predicate devices

<i>Trade or proprietary or model name</i>	SurgiCase Orthopaedics system
<i>510(k) number</i>	K112389
<i>Decision date</i>	07/20/2012
<i>Product code</i>	PBF
<i>Manufacturer</i>	Materialise N.V.

Device Information

Description and functioning of the device

The SurgiCase Orthopaedics system is intended to be used as a surgical instrument to transfer a pre-surgical plan to the surgery with osteotomies on upper extremity orthopedic procedures and osteotomies around the knee.

The SurgiCase Orthopaedics system is composed of two components: SurgiCase Connect (software) and SurgiCase Guides (hardware).

SurgiCase Connect is a medical device for Materialise and a surgeon for pre-surgical simulation and evaluation of surgical treatment options. This includes transferring, visualizing, measuring, annotating and editing medical data.

The **SurgiCase Guides** are patient specific templates that are designed and manufactured based on a pre-surgical software plan for a specific patient. In surgery these guides are used to assist a surgeon in guiding the marking of bone and/or guiding surgical instruments to cut and drill according to the pre-surgical plan.

All guides are individually designed and manufactured for each patient using a design and manufacturing process with strict procedures and work instructions to guarantee guides that consistently perform in a safe and effective way. Part of this process is a scientific Stability Model which measures the sensitivity of a guide to movement during surgery. The use of this Stability Model ensures a stable position on the patient's anatomy for accurate guiding of surgical instruments. The Stability Model is anatomy independent, thus it can be applied to any bony structure in upper extremity surgical procedures and osteotomies around the knee.

Intended use

The **SurgiCase Orthopaedics** system is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies for upper extremity orthopedic surgical procedures and osteotomies around the knee.

The system is to be used for adult patients.

SurgiCase Guides are intended for single use only.

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent in intended use, design, functionality, fundamental technology, materials and performance characteristics to the predicate device.

- Both subject device and predicate device are to be used as a surgical instrument to assist the surgeon in pre-operative planning and evaluation of surgical treatment options.
- The guides of the subject and predicate devices are intended to guide the marking of bone and/or guiding the surgical instruments in surgical procedures.
- The guides of the subject and predicate devices are designed and manufactured from reconstructed three-dimensional models of the patient's anatomy.
- The guides of the subject and predicate devices are made of the same material and follow the same manufacturing process.
- The guide performance of subject and predicate device is guaranteed once the stable fit of the guide on the patient's anatomy is obtained, no matter the shape of the bone.
- Both subject device and predicate device use the same scientific Stability Model to ensure the most stable fit of the guide on the patient's anatomy.
- The software component of the subject and predicate device are intended for use as medical device for Materialise and a surgeon for pre-surgical simulation and evaluation of surgical treatment options, which includes transferring, visualizing, measuring, annotating and editing medical data.
- The software component of the subject device is the same software component of the predicate device, only updated with user interface improvements and minor functional additions.
- The software component of the subject and predicate device functions exactly the same.
- The software component of the subject and predicate device utilized the same programming language and operating system.
- The guides and software of the subject and predicate device have been developed by the same manufacturing company (Materialise NV), based on the same fundamental technology and in-house knowledge and followed the same internal quality procedures and work instructions for design, development, testing and validation.

The only difference is the surgical region where the guides will be applied: lower extremity around the knee for the subject device versus upper extremity for the predicate device. There is no functional difference between the subject and predicate device guides. The guides are able to obtain a similar level of performance for both predicate and subject device. The difference between the subject device and the predicate device does not affect the safety and effectiveness of the device when used as labeled.

Performance data

Non-clinical testing

The **SurgiCase Connect** software has been validated for its intended use by internal and external user testing and observations. Verification tests are derived from the specifications and ensures that all controls and features are functioning properly. The results from this verification and validation testing demonstrate the device's safety and effectiveness is substantially equivalent to the predicate device for use as intended.

SurgiCase Guides were validated through non-clinical studies using bone models and cadaver specimens:

- Bone model tests: On a series of femoral and tibial models, Surgicase Guides were designed and applied according to a pre-operative plan. The planned versus achieved corrected models were compared. All results were within the preset acceptance criteria.
- Cadaveric tests: On a series of cadaveric specimens, Surgicase Guides were designed and applied according to a pre-operative plan. The planned versus achieved corrected specimens were compared. All results were within the preset acceptance criteria.

Biocompatibility test, sterility test, sterilization dimensional stability test, cleaning validation test and packaging and shipment test were performed to assess the safety and effectiveness of the SurgiCase Guides. Testing verified that the accuracy and performance of the device is adequate to perform as intended. Additionally, the use of a scientific Stability Model ensures the most stable position on the patient's anatomy for accurate guiding of surgical instruments.

Clinical testing

Non-clinical testing was sufficient to demonstrate that the device's safety and effectiveness is substantially equivalent to the predicate device.

Other performance data

Retrospective analysis of clinical cases performed in Europe confirms the subject device's safety and effectiveness is substantially equivalent to the predicate device to use as intended based on surgeon evaluation of expected outcome.

These clinical cases are also described in the following paper:

Victor J, Premanathan A, Virtual 3D planning and patient specific guides for osteotomies around the knee: a feasibility and proof-of-concept study, *BONE & JOINT JOURNAL* 2013 .95B(11, suppl. A).p.153-158

Summary

All non clinical testing and other performance data indicate that the subject device is as safe, as effective, and performs as well as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

Materialise N.V.
Mr. Oliver Clemens
Technologielaan 15
Leuven, 3001 BE

Re: K132290
Trade/Device Name: Surgicase orthopaedics system, surgicase connect, surgicase guides
Regulation Number: 21 CFR 888.3030
Regulation Name: Orthopaedic Surgical Planning And Instruments Guide
Regulatory Class: Class II
Product Code: PBF
Dated: February 21, 2014
Received: February 24, 2014

Dear Mr. Clemens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132290

Device Name
SurgiCase Orthopaedics system

Indications for Use (Describe)

The SurgiCase Orthopaedics system is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies for upper extremity orthopedic surgical procedures and osteotomies around the knee.

The system is to be used for adult patients.

SurgiCase Guides are intended for single use only.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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